

Introduced by Senator Johnson

February 20, 2004

An act to amend Sections 100700, 100710, 100715, 100720, 100735, 100745, and 100750 of, and to add Sections 100701, 100702, and 100703 to, the Health and Safety Code, relating to laboratories.

LEGISLATIVE COUNSEL'S DIGEST

SB 1623, as introduced, Johnson. Laboratories: licensing and accreditation.

Under existing law, the State Department of Health Services is required to adopt and publish regulations to be used in approving and governing the operation of laboratories conducting testing by or for law enforcement agencies of blood, urine, or tissue for the purposes of determining the concentration of ethyl alcohol in the blood of persons involved in traffic accidents or in traffic violations, and the testing of breath samples under the same circumstances.

This bill would require the department to adopt and publish regulations, that incorporate model specifications published by the National Highway Traffic Safety Administration, to be used in approving and governing the operation of laboratories and law enforcement agencies engaging in breath testing under the circumstances described above. The bill would require the department to convene a review committee, prior to adopting the regulations, and to submit the proposed regulations to the committee for review.

This bill would additionally authorize the performance of the blood, urine, or tissue tests described above by a laboratory holding a current accreditation to perform the test from the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB). The bill would require the department to issue a license to a laboratory



so accredited, and would exempt these laboratories from departmental regulations governing blood, urine, and tissue tests, except with respect to proficiency testing requirements. The bill would establish procedures that permit laboratories accredited by the ASCLD/LAB to appeal the director's determinations. The bill would require the department to accept proof of inspection by the ASCLD/LAB in satisfaction of the department's existing inspection requirement. The bill would make additional conforming changes to existing law.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 100700 of the Health and Safety Code
2 is amended to read:

3 100700. The department shall adopt and publish regulations
4 to be used in approving and governing the operation of laboratories
5 engaging in the performance of tests referred to in ~~Sections 100710~~
6 ~~and 100715~~, *Section 100710*, including the qualifications of the
7 employees who perform the tests, that ~~it determines~~ are
8 *determined, pursuant to Sections 100701 and 100703, to be*
9 reasonably necessary to ensure the competence of the laboratories
10 and employees to prepare, analyze, and report the results of the
11 tests.

12 SEC. 2. Section 100701 is added to the Health and Safety
13 Code, to read:

14 100701. On or before July 1, 2005, the department shall adopt
15 and publish regulations to be used in approving and governing the
16 operation of laboratories and law enforcement agencies engaging
17 in the performance of the tests referred to in Section 100715 in
18 accordance with the findings of the laboratory directors review
19 panel. The laboratory directors review panel shall be comprised of
20 three California crime laboratory directors, or their designees,
21 including one from the state, one from a county, and one from a
22 city. The regulations shall incorporate the Model Specifications
23 for Evidential Breath Testing Devices and the Model
24 Specifications for Calibrating Units for Breath Alcohol Testers as
25 published in the Federal Register by the National Highway Traffic
26 Safety Administration of the United States Department of
27 Transportation. The revised regulations shall be adopted only after

1 the department has convened a review committee pursuant to
2 Section 100703, and the review committee has determined that the
3 regulations are limited to requirements that the review committee
4 finds are reasonably necessary to ensure the competence of the
5 laboratories or persons conducting the tests.

6 SEC. 3. Section 100702 is added to the Health and Safety
7 Code, to read:

8 100702. (a) Regulations adopted pursuant to this article
9 governing the tests referred to in Section 100710 shall not apply
10 to a laboratory holding a current accreditation to perform the tests
11 referred to in Section 100710 from the American Society of Crime
12 Laboratory Directors/Laboratory Accreditation Board
13 (ASCLD/LAB). ASCLD/LAB accredited laboratories shall
14 ensure that their published standards, as they relate to proficiency
15 testing, quality control, and inspections, are in compliance with
16 Title 17 of the California Code of Regulations.

17 (b) If, at any time, the director determines that standards
18 published by the ASCLD/LAB do not meet the standards
19 contained in the department's regulations, the director shall,
20 within 30 days of making that determination, send a written
21 account itemizing the ways in which ASCLD/LAB standards do
22 not meet those of the department to any laboratory that has
23 presented proof of a current accreditation by the ASCLD/LAB to
24 perform the tests referred to in Section 100710.

25 (c) Any laboratory to which a written account of the
26 department's determination is required to be sent pursuant to
27 subdivision (b) may file with the director an objection to that
28 written account within 60 days of the date of issuance of the written
29 account. If an objection is filed pursuant to this subdivision, the
30 director shall, within 60 days of receiving the objection, convene
31 a laboratory directors review panel comprised of three California
32 crime laboratory directors or their designees, including one from
33 the state, one from a county, and one from a city, to resolve the
34 contested issues. The laboratory directors review panel shall
35 submit its findings to the director no later than 60 days from the
36 date of the convening of the panel. The panel's decision shall be
37 final, and the director shall implement the findings of the panel.

38 (d) Notwithstanding subdivision (a), the department may
39 continue to impose proficiency testing requirements on any
40 laboratory engaging in the performance of tests referred to in

1 Section 100710. All licensed laboratories shall be required to
2 participate in, and pay the fees of, an ASCLD/LAB approved
3 proficiency test program.

4 SEC. 4. Section 100703 is added to the Health and Safety
5 Code, to read:

6 100703. (a) On or before July 1, 2005, and at least once in
7 each five-year period thereafter, or within 60 days of receipt of a
8 request by a member of the review committee, the department
9 shall convene a review committee to evaluate regulations
10 proposed or adopted by the department pursuant to this article. The
11 review committee shall be selected by the representative agencies,
12 and shall have seven members, including one person representing
13 each of the following:

- 14 (1) Public prosecuting attorneys.
- 15 (2) Law enforcement agencies.
- 16 (3) Public defenders.
- 17 (4) Coroners, pathologists, or medical examiners.
- 18 (5) California Association of Criminalists.
- 19 (6) California Association of Toxicologists.
- 20 (7) California Association of Crime Laboratory Directors.

21 (b) The review committee shall examine the regulations
22 adopted by the department pursuant to this article, and recommend
23 revisions that will limit the regulations to requirements the review
24 committee determines are reasonably necessary to ensure the
25 competence of the laboratories and employees to prepare, analyze,
26 and report the results of the test.

27 (c) The department shall adopt the revisions recommended by
28 the review committee.

29 SEC. 5. Section 100710 of the Health and Safety Code is
30 amended to read:

31 100710. The testing by or for law enforcement agencies of
32 blood, urine, or tissue for the purposes of determining the
33 concentration of ethyl alcohol in the blood of persons involved in
34 traffic accidents or in traffic violations shall be performed only by
35 a laboratory approved and licensed by the director for the
36 performance of these tests, *or by a laboratory holding a current*
37 *accreditation to perform those tests from the American Society of*
38 *Crime Laboratory Directors/ Laboratory Accreditation Board*
39 *(ASCLD/LAB).*

1 SEC. 6. Section 100715 of the Health and Safety Code is
2 amended to read:

3 100715. The testing of breath samples by or for law
4 enforcement agencies for purposes of determining the
5 concentration of ethyl alcohol in the blood of persons involved in
6 traffic accidents or in traffic violations shall be performed in
7 accordance with regulations adopted by the department *pursuant*
8 *to Section 100701*.

9 The regulations shall establish the procedures to be used by law
10 enforcement agencies in administering breath tests for the
11 purposes of determining the concentration of ethyl alcohol in a
12 person's blood. The regulations shall be adopted and published in
13 accordance with Chapter 3.5 (commencing with Section 11340) of
14 Part 1 of Division 3 of Title 2 of the Government Code.

15 SEC. 7. Section 100720 of the Health and Safety Code is
16 amended to read:

17 100720. Each laboratory in the state that performs the tests
18 referred to in Sections 100710 and 100715, shall be licensed by the
19 director. *The director shall issue a license to any laboratory that*
20 *presents proof of a current accreditation to perform the tests*
21 *referred to in Section 100710 from the American Society of Crime*
22 *Laboratory Directors/Laboratory Accreditation Board*
23 *(ASCLD/LAB)*. Each of these laboratories, other than a laboratory
24 operated by the state, city or county or other public agency shall
25 upon application for licensing pay a fee to the department in an
26 amount, to be determined by the department, that will reimburse
27 the department for the costs incurred by the department in the
28 issuance and renewal of these licenses. On or before each January
29 1 of each year thereafter, each of these laboratories shall pay to the
30 department a fee so determined by the department.

31 SEC. 8. Section 100735 of the Health and Safety Code is
32 amended to read:

33 100735. (a) Every approved and licensed laboratory shall be
34 ~~periodically inspected~~ *available for periodic inspection* by the
35 department. Reports of each inspection shall be prepared on forms
36 furnished by the department and shall be filed with the department.

37 (b) *The department shall accept proof of inspection by the*
38 *American Society of Crime Laboratory Directors/Laboratory*
39 *Accreditation Board (ASCLD/LAB), with respect to a laboratory*

1 *exempt from departmental regulatory requirements pursuant to*
2 *Section 100702, as satisfying the requirements of this section.*

3 SEC. 9. Section 100745 of the Health and Safety Code is
4 amended to read:

5 100745. The director may deny a license if the applicant or
6 any partner, officer or director thereof:

7 (a) ~~Fails~~ *Except as provided in Section 100702, fails* to meet the
8 qualifications established by the department pursuant to this
9 article for the issuance of the license applied for.

10 (b) Was previously the holder of a license issued under this
11 article that was revoked and never reissued or that was suspended
12 and the terms of the suspension have not been fulfilled.

13 (c) Has committed any act involving dishonesty, fraud, or
14 deceit whereby another was injured or whereby the applicant has
15 benefited.

16 SEC. 10. Section 100750 of the Health and Safety Code is
17 amended to read:

18 100750. The director may suspend, revoke, or take other
19 disciplinary action against a licensee as provided in this article if
20 the licensee or any partner, officer or director thereof:

21 (a) ~~Violates~~ *Except as provided in Section 100702, violates* any
22 of the regulations adopted by the department pursuant to this
23 article.

24 (b) Commits any act of dishonesty, fraud, or deceit whereby
25 another is injured or whereby the licensee benefited.

26 (c) Misrepresents any material fact in obtaining a license.

27 (d) *With respect to a laboratory exempt from departmental*
28 *regulatory requirements pursuant to Section 100702, has its*
29 *accreditation by the Proficiency Review Committee of the*
30 *American Society of Crime Laboratory Directors/Laboratory*
31 *Accreditation Board suspended or revoked.*

